

### **REMARKS**

Claims 1-4, 8-11, 23, 27, 28, 31, and 34-57 are pending in this application. Applicants have amended claims 1, 3, 8, 9, 11, and 23, and canceled claims 5, 22, 24-26, 29, 30, 32, and 33 without prejudice or disclaimer. Claims 34-57 are new. Support for the amendments and new claims can be found in the application as filed, e.g., at page 2, lines 16-20 and 31-32; page 3, lines 21-29; page 4, line 8; page 36, lines 1-3; page 65, line 6; and the Examples on pages 71-73. No new matter has been added.

Claims 1-4, 8-11, 23, 27, 28, 31, and 34-57 read on the species of SIRT1 protein.

#### **Interview Summary**

Applicants thank Examiner Lee for conducting a telephonic interview with Applicants' undersigned representative on December 5, 2008. During the interview, the supplemental restriction requirement and the written description and enablement rejections were discussed.

#### **Withdrawn Objections**

Applicants thank the Examiner for withdrawing the previously-raised objections to the specification and to claims 4 and 6-8.

#### **Withdrawn Rejections**

Applicants thank the Examiner for withdrawing the previously-raised written description rejection to claims 1-11.

#### **Claim Objections**

*Claims 1, 8, 9, 11, 24, 29, and 32.* The Office maintains its objections to claims 1, 8, 9, 11, 24, 29, and 32 for allegedly containing non-elected subject matter (pages 6-7 of the Office Action). Applicants respectfully submit that the claim amendments and claim cancellations presented herein overcome this objection and request withdrawal of the same.

*Claims 1, 9, 11, 24, 29, and 32.* The Office at page 7 objects to the recitation of "SIR protein" in these claims. Applicants respectfully submit that the claim amendments and claim cancellations presented herein have removed this term from these claims, thereby obviating this objection.

*Claims 24, 29, and 32.* The Office objects to the term “a nucleic acid” recited in these claims (*Id.*). Claims 24, 29, and 32 have been canceled, thereby obviating this objection.

*Claim 3.* The Office suggests amending claim 3 to recite “a full length cytochrome c polypeptide.” Applicants have amended this claim as suggested by the Office and respectfully request withdrawal of this objection.

#### Election/Restriction

At pages 2-6 of the Office Action, the Office indicates that the species of SIRT2, SIRT3, SIRT4, SIRT5, SIRT6, and SIRT7 have been withdrawn from consideration in the present application.

Applicants respectfully disagree with the Office's position, for example, as these species of SIRT proteins share a common utility and a substantial structural feature essential to that utility, and thus share unity of invention. However, solely in the interest of expediting prosecution, the pending claims have been amended to recite SIRT1 (SEQ ID NO:1).

#### 35 U.S.C. §112, 2<sup>nd</sup> Par.

*Claims 1-5, 8-11, and 22-33.* The Office at page 8 rejects claims 1-5, 8-11, and 22-33 are allegedly being indefinite, specifically, because it is allegedly “unclear and indefinite as to whether or not SIRT1 is being limited to SEQ ID NO:1 ...”

Claims 5, 22, 24-26, 29, 30, 32, and 33 have been canceled, obviating the rejection with respect to these claims. Applicants have amended claims 1, 9, and 11 as indicated herein, and submit that these amendments overcome this rejection to claims 1, 9, 11, and their rejected dependencies. Withdrawal of this rejection is respectfully requested.

*Claims 24-26, 29, 30, 32, and 33.* The Office rejects these claims as allegedly being indefinite. Claims 24-26, 29, 30, 32, and 33 have been canceled, thereby obviating this rejection.

*Claims 1-5, 8-11, and 22-33.* At page 10, the Office rejected these claims as allegedly being indefinite for the recitation of “a cytochrome c polypeptide.”

Claims 22, 24-26, 29, 30, 32, and 33 have been canceled, obviating the rejection with respect to these claims.

In response to the Office's position, Applicants have canceled claim 5, thus addressing the alleged indefiniteness issue. Further, claims 1, 9, and 11 have been amended to specify that the cytochrome c is a substrate. Applicants submit that the amendments overcome the rejection and request withdrawal of the same.

*Claims 11 and 32.* The Office rejects claims 11 and 32 as allegedly being indefinite for reciting, "contacting a cell which expresses the SIR polypeptide and a cytochrome c polypeptide with the test compound" because, according to the Office, "the steps prior to the noted step already require contacting the SIR polypeptide and evaluating whether there is a modulation. Essentially, the noted step is repeating the same steps prior to the noted phrase" (Office Action at page 11).

Claim 32 has been canceled, obviating the rejection with respect to this claim.

Regarding claim 11, Applicants point out that the claim recites, in part, contacting a SIR polypeptide having deacetylase activity with a test compound, in the presence of a cytochrome c polypeptide, **in vitro**, and evaluating if the test compound modulates **interaction** between the SIR polypeptide and the cytochrome c polypeptide. The claim also recites, in part, the steps of contacting a cultured cell which expresses the SIR polypeptide and a cytochrome c polypeptide with the test compound, and determining if the test compound modulates acetylation of the cytochrome c polypeptide in the cell.

Thus, claim 11 does not recite repeating steps, but rather recites distinct steps: evaluating if a test compound modulates **interaction** between a SIR polypeptide and cytochrome c **in vitro**, and also evaluating if the test compound modulates acetylation of the cytochrome c in a cultured cell. Applicants submit that claim 11 is not indefinite and respectfully request that this rejection be withdrawn.

35 U.S.C. §112, 1<sup>st</sup> Par., Written Description

The Office at pages 11-14 rejects claims 24-26, 29, 30, 32, and 33 for allegedly failing to satisfy the written description requirement.

These claims have been canceled in the present amendment and reply. Withdrawal of this rejection is respectfully requested.

35 U.S.C. §112, 1<sup>st</sup> Par., Enablement

At pages 15-21 of the Office Action, the Office alleges that claims 1-5, 8-10, and 22-30 are not enabled.

Claims 5, 22, 24-26, 29, and 30 have been canceled, obviating the rejection with respect to these claims.

Regarding claims 1-4, 8-10, 23, 27, and 28, Applicants respectfully disagree with the Office's position. However, in the interest of advancing prosecution, Applicants have amended claims 1, 9, and 11. Claim 1 recites that the contacting step occurs in vitro, claim 9 recites that the contacting step occurs in a cultured cell, and claim 11 recites that a contacting step occurs in in vitro and that another contacting step occurs in a cultured cell. The Office at page 15 indicates that such methods are enabled by the present application. Indeed, the application sets forth detailed guidance and working examples demonstrating the use of the claimed methods. See, e.g., page 35, line 17 to page 42, line 3 ("Screening Assays"), page 42, line 5 to page 49, line 14 ("*In vitro* Assays"), page 49, line 16 to page 51, line 19 ("Cell-Based Assays"), and page 71, line 29 to page 73, line 5 ("EXAMPLES"). For at least these reasons, Applicants submit that the methods of claims 1-4, 8-10, 23, 27, and 28 are enabled and that a skilled practitioner can practice the claimed methods without undue experimentation. Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

For at least the reasons stated above, Applicants respectfully submit that all pending claims are in condition for allowance, which action is expeditiously requested. Applicants do not concede any positions of the Examiner that are not expressly addressed above, nor do Applicants concede that there are not other good reasons for patentability of the presented claims or other claims.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicants hereby request any necessary extension of time. A petition of time is being filed herewith. The extension fee and excess claim fee for 15 claims is being paid by deposit account authorization. Please charge any deficiency to Deposit Account No. 50/2762 referencing attorney docket no. E2023-7020US

Respectfully submitted,  
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Docket No.: E2023-7020US  
Date: January 28, 2009